

## Ipsen announces Dysport® (abobotulinumtoxinA) co-promotion agreement with Saol Therapeutics to expand commercial reach in the United States

*Saol sales team to promote Dysport® for select approved therapeutic indications in U.S. hospitals*

**BASKING RIDGE, N.J., June 30, 2017** – Ipsen Biopharmaceuticals, Inc., an affiliate of Ipsen SA (Euronext: IPN; ADR: IPSEY) (Ipsen), today announced that it has entered into an exclusive, three-year agreement with Saol Therapeutics Inc. to promote Dysport® (abobotulinumtoxinA) for injection for approved therapeutic indications in adult spasticity and pediatric lower limb spasticity in the United States.

“By adding the Saol team's extensive experience with physicians in the hospital setting to our existing efforts, we are able to educate more U.S. healthcare professionals on Dysport®,” said Cynthia Schwalm, President, North American Commercial Operations, Ipsen. “As the only botulinum toxin approved by the FDA for the treatment of spasticity in adults in upper and lower limbs, and also for the treatment of lower limb spasticity in children ages two and older, it is critical to raise awareness of Dysport® as a potential option for appropriate patients.”

Dysport® and all botulinum toxin products have a Boxed Warning which states that the effects of the botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Those symptoms include swallowing and breathing difficulties that can be life-threatening. Dysport® is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components; or in the presence of infection at the proposed injection site(s); or in patients known to be allergic to cow's milk protein. The potency Units of Dysport® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products. Please see below for additional Important Safety Information.

Under the terms of the agreement, Saol's sales force will promote Dysport® to healthcare professionals largely in the hospital setting beginning August 2017. Ipsen will maintain its current number of sales representatives fully dedicated to Dysport® including all its therapeutic indications. Additional details of the agreement are not disclosed.

Based in Roswell, GA, Saol Therapeutics is a privately held specialty pharmaceutical company focused on providing therapies to patients with unmet medical needs. The company has a strategic emphasis on spasticity and neurologic areas. Saol currently markets Lioresal® Intrathecal (baclofen injection), the first FDA-approved intrathecal baclofen for the treatment of severe spasticity. By detailing both products, Saol believes it can further support healthcare professionals and the patients they serve with forms of spasticity that each product is FDA approved to treat.

“At Saol, we are committed to the treatment of patients with spasticity. As a cornerstone to that, we believe it is important that physicians are made aware of available treatment options,” said Saol Therapeutics Chief Executive Officer, David Penake. “Our agreement with Ipsen helps us in

that mission. It also allows us to align with a company that matches our passion for doing everything we can to support and educate physicians. We look forward to working with Ipsen and growing our organization, with the goal of helping patients in the United States.”

Please find included Important Safety Information – including **BOX WARNINGS** – for Dysport® and Lioresal® Intrathecal (baclofen injection).

### **About Dysport® (abobotulinumtoxinA) for Injection**

Dysport® is an injectable form of botulinum toxin type A (BoNT-A), which is isolated and purified from Clostridium bacteria producing BoNT-A. It is supplied as a lyophilized powder. Dysport® has approved indications in the United States for the treatment of adults with Cervical Dystonia (CD) and for the treatment of spasticity in adult patients. Dysport® is also the first and only FDA-approved botulinum toxin for the treatment of lower limb spasticity in pediatric patients two years of age and older.

### **About IPSEN CARES®**

IPSEN CARES® (Coverage, Access, Reimbursement, & Education Support) is dedicated to ensuring patients, providers and caregivers have the resources needed to help access the Ipsen medications that are critical to managing their conditions. IPSEN CARES® is staffed Monday to Friday by experts who can assist with a broad range of medical, educational, logistical and coverage information regarding Ipsen medicines. Involving the entire treatment team that surrounds patients on a daily basis, IPSEN CARES® can provide benefits verification (research of a patient’s medical or pharmacy benefit insurance coverage); prior authorization information; a patient assistance program (free medications for uninsured patients); co-pay assistance programs for eligible patients; billing and coding support; coordination with specialty pharmacies. Additional information is also available by visiting (<http://www.ipsecares.com>).

## **INDICATIONS AND IMPORTANT SAFETY INFORMATION**

### **DYSPORT® INDICATIONS**

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:

- Spasticity in adult patients
- Adults with cervical dystonia
- Lower limb spasticity in pediatric patients 2 years of age and older.

The safety and effectiveness of Dysport® injected into upper limb muscles or proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established. Safety and effectiveness in pediatric patients with lower limb spasticity below 2 years of age have not been evaluated.

Safety and effectiveness in pediatric patients with cervical dystonia or upper limb spasticity have not been established.

### **IMPORTANT SAFETY INFORMATION**

#### **Warning: Distant Spread of Toxin Effect**

**Postmarketing reports indicate that the effects of Dysport® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have**

**been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended total dose.**

### **Contraindications**

Dysport® is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components; or in the presence of infection at the proposed injection site(s); or in patients known to be allergic to cow's milk protein. Hypersensitivity reactions including anaphylaxis have been reported.

### **Warnings and Precautions**

#### **Lack of interchangeability between botulinum toxin products**

The potency Units of Dysport® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products, and, therefore, units of biological activity of Dysport® cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.

#### **Dysphagia and Breathing Difficulties**

Treatment with Dysport® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant side effects occur, additional respiratory muscles may be involved (see Boxed Warning). Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several weeks, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.

#### **Pre-existing Neuromuscular Disorders**

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of Dysport®.

#### **Human Albumin and Transmission of Viral Diseases**

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

### **Intradermal Immune reaction**

The possibility of an immune reaction when injected intradermally is unknown. The safety of Dysport® for the treatment of hyperhidrosis has not been established. Dysport® is approved only for intramuscular injection.

### **Adverse reactions**

Most common adverse reactions ( $\geq 2\%$  and greater than placebo in either Dysport® group) in **adults with upper limb spasticity** for Dysport® 500 Units, Dysport® 1000 Units, and Placebo, respectively, were: nasopharyngitis (4%, 1%, 1%), urinary tract infection (3%, 1%, 2%), muscular weakness (2%, 4%, 1%), musculoskeletal pain (3%, 2%, 2%), dizziness (3%, 1%, 1%), fall (2%, 3%, 2%), and depression (2%, 3%, 1%).

Most common adverse reactions ( $\geq 5\%$  and greater than placebo in either Dysport® group) in **adults with lower limb spasticity** for Dysport® 1000 Units, Dysport® 1500 Units, and Placebo, respectively, were: falls (9%, 6%, 3%), muscular weakness (2%, 7%, 3%), pain in extremity (6%, 6%, 2%). Muscular weakness was reported more frequently in women (10%) treated with 1500 units of Dysport compared to men (5%).

Most common adverse reactions ( $\geq 5\%$  and greater than placebo) in **adults with cervical dystonia** for Dysport® 500 Units and Placebo, respectively, were: muscular weakness (16%, 4%), dysphagia (15%, 4%), dry mouth (13%, 7%), injection site discomfort (13%, 8%), fatigue (12%, 10%), headache (11%, 9%), musculoskeletal pain (7%, 3%), dysphonia (6%, 2%), injection site pain (5%, 4%), and eye disorders (7%, 2%).

Most common adverse reactions ( $\geq 10\%$  in any group and greater than placebo) in **pediatric patients with lower limb spasticity** for Dysport® 10 Units/kg, 15 Units/kg, 20 Units/kg, or 30 Units/kg; and Placebo, respectively, were: upper respiratory tract infection (9%, 20%, 5%, 10%, 13%), nasopharyngitis (9%, 12%, 16%, 10%, 5%), influenza (0%, 10%, 14%, 3%, 8%), pharyngitis (5%, 0%, 11%, 3%, 8%), cough (7%, 6%, 14%, 10%, 6%), and pyrexia (7%, 12%, 8%, 7%, 5%).

### **Drug interactions**

Co-administration of Dysport® and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of botulinum toxin may be potentiated. Use of anticholinergic drugs after administration of Dysport® may potentiate systemic anticholinergic effects such as blurred vision. The effect of administering different botulinum neurotoxins at the same time or within several months of each other is unknown. Excessive weakness may be exacerbated by another administration of botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of Dysport®.

### **Use in Pregnancy**

Based on animal data Dysport® may cause fetal harm. There are no adequate and well-controlled studies in pregnant women. Dysport® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### **Pediatric Use**

Based on animal data Dysport® may cause atrophy of injected and adjacent muscles; decreased bone growth, length, and mineral content; delayed sexual maturation; and decreased fertility.

### **Geriatric Use**

In general, elderly patients should be observed to evaluate their tolerability of Dysport®, due to the greater frequency of concomitant disease and other drug therapy. Subjects aged 65 years and over who were treated with DYSPORT® for lower limb spasticity reported a greater percentage of fall and asthenia as compared to those younger (10% versus 6% and 4% versus 2%, respectively).

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see Dysport® [Full Prescribing Information](#) including **Boxed Warning** and [Medication Guide](#).

## **INDICATIONS AND IMPORTANT SAFETY INFORMATION**

### **Lioresal® Intrathecal (baclofen injection)**

#### Indications and Usage

- Lioresal® Intrathecal (baclofen injection) is a muscle relaxant and antispastic that is indicated for use in the management of severe spasticity of cerebral or spinal origin.
- Lioresal® Intrathecal is intended for use by the intrathecal route in single bolus test doses (via spinal catheter or lumbar puncture) and, for chronic use, only in implantable pumps approved by the FDA specifically for the administration of Lioresal® Intrathecal into the intrathecal space.
- Lioresal® Intrathecal via an implantable pump should be reserved for patients unresponsive to oral baclofen therapy or those who experience intolerable CNS side effects at effective doses.
- Patients with spasticity due to traumatic brain injury should wait at least one year after the injury before consideration of long term intrathecal baclofen therapy.
- Prior to implantation of a device for chronic intrathecal infusion of Lioresal® Intrathecal, patients must show a response to Lioresal® Intrathecal in a screening trial. Please review the dosing and administration section of the Lioresal® Intrathecal prescribing information for further details.

**Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.**

**Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional postimplant clinician and patient information (see WARNINGS).**

#### Contraindications

- Hypersensitivity to baclofen
- Lioresal® Intrathecal is not recommended for intravenous, intramuscular, subcutaneous or epidural administration.

#### Select Warnings and Precautions

- It is mandatory that all patients, caregivers, and treating physicians receive adequate information regarding the risks of the mode of treatment. Instruction should be given on signs and symptoms of overdose, procedures to be followed in the event of an overdose, and proper home care of the pump and insertion site.
- Due to the possibility of life-threatening CNS depression, cardiovascular collapse, and/or respiratory failure, physicians must be adequately trained and educated in chronic intrathecal infusion therapy.
- Patients should be infection-free prior to both a screening trial and a pump implantation. The presence of infection may interfere with an assessment of the patient's response to bolus Lioresal® Intrathecal, increase the risk of surgical complications and complicate dosing.
- Reservoir refilling must be performed by fully trained and qualified personnel following the directions provided by the pump manufacturer. Extreme caution must be used when filling an FDA approved implantable pump, following strict aseptic technique and ensuring refill directly into the reservoir and not the catheter access port.
- An attempt should be made to discontinue concomitant oral antispasticity medication to avoid possible overdose or adverse drug interactions, either prior to screening or following implant and initiation of chronic Lioresal® Intrathecal infusion.
- Following pump implantation, and for each adjustment of the dosing rate of the pump and/or concentration of Lioresal® Intrathecal, the patient should be monitored closely until it is certain the patient's response to the infusion is acceptable and reasonably stable.
- Early symptoms of baclofen withdrawal may include return of baseline spasticity, pruritus, hypotension and paresthesias.
- Priapism may develop or recur if treatment with intrathecal baclofen is interrupted.

- Signs of overdose may appear suddenly or insidiously, and a massive overdose may present as coma. Less sudden and/or less severe forms of overdose may present with signs of drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia and loss of consciousness progressing to coma.
- Should overdose appear likely, the patient should be taken immediately to a hospital for assessment and emptying of pump reservoir.
- Except in overdose related emergencies, the dose of Lioresal® Intrathecal should ordinarily be reduced slowly if the drug is discontinued for any reason.

## Adverse Reactions

### Common Adverse Reactions

- The most frequent drug adverse events vary by indication but include: hypotonia (34.7%), somnolence (20.9%), headache (10.7%), convulsion (10.0%), dizziness (8.0%), urinary retention (8.0%), nausea (7.3%), and paresthesia (6.7%). Dosing and programming errors may result in clinically significant overdose or withdrawal. Acute massive overdose may result in coma and may be life threatening.
- Drowsiness has been reported in patients on Lioresal® Intrathecal. Patients should be cautioned regarding the operation of automobiles or other dangerous machinery and activities made hazardous by decreased alertness. Patients should also be cautioned that the central nervous system depressant effects of Lioresal® Intrathecal may be additive to those of alcohol and other CNS depressants.

### Serious Adverse Reactions

- Seizures have been reported during overdose and with withdrawal from Lioresal® Intrathecal as well as in patients maintained on therapeutic doses of Lioresal® Intrathecal.
- Fatalities have been reported with Lioresal® Intrathecal use.

### Postmarketing Experience

- The following adverse events have been reported during post-approval use of Lioresal® Intrathecal.
  - Musculoskeletal – The onset of scoliosis or worsening of a pre-existing scoliosis has been reported.
  - Urogenital – Sexual dysfunction in men and women including decreased libido and orgasm dysfunction have been reported.

## Use in Specific Populations

- There are no adequate and well controlled studies in pregnant women. Lioresal® Intrathecal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing mothers should exercise caution, as oral baclofen has been shown to pass into milk at therapeutic doses.
- Safety and effectiveness in pediatric patients below the age of 4 have not been established.
- Patients suffering from psychotic disorders, schizophrenia, or confusional states should be treated cautiously with Lioresal® Intrathecal and kept under careful surveillance.
- Lioresal® Intrathecal should be given with caution in patients with impaired renal function. Dose reduction may be necessary.
- Lioresal® Intrathecal should be used with caution in patients with a history of autonomic dysreflexia.

For more information, including **BOX WARNING**, refer to Lioresal® Intrathecal (baclofen injection) prescribing information, located [here](#).

### **About Ipsen in North America**

Ipsen Biopharmaceuticals, Inc. is the US affiliate of Ipsen, a global specialty-driven biopharmaceutical group. The US head office is located in Basking Ridge, New Jersey. Ipsen Biopharmaceuticals Canada, Inc. is an integrated business unit within North America and has its head office located in Mississauga, Ontario. Ipsen Bioscience, Inc., the Ipsen US research and development center focused on the discovery of highly differentiated and competitive products in oncology and rare diseases, is located in Cambridge, Massachusetts. At Ipsen Bioscience, we focus on creating a highly cooperative and passionate R&D organization through partnerships, innovation, and continuous learning to effectively deliver new treatments for patients. At Ipsen, we focus our resources, investments, and energy on discovering, developing, and commercializing new therapeutic options for oncologic, neurologic, and endocrine diseases. For more information on Ipsen in North America, please visit [www.ipsenus.com](http://www.ipsenus.com) or [www.ipsen.ca](http://www.ipsen.ca).

### **About Ipsen**

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neurosciences and Rare Diseases. Its commitment to oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales close to €1.6 billion in 2016, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,100 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depository Receipt program (ADR: IPSEY). For more information on Ipsen, visit [www.ipsen.com](http://www.ipsen.com).



## Forward Looking Statements

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favorable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfill their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial

position or performance. The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.

**For further information:**

**Media**

Marisol Peron  
Vice President, North American Internal & External  
Communications  
Tel.: 908-275-6330  
E-mail: marisol.peron@ipsen.com

Elliot Fox  
W2O Group  
Tel.: 212-257-6724  
E-mail: efox@w2ogroup.com

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Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-Unit vials. DYSPOORT is a registered trademark of Ipsen Biopharm Limited. IPSEN CARES is a registered trademark of Ipsen S.A. Lioresal® is a registered trademark of Saol International Limited Corporation.

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